K024069

JAN 0 8 2003

510(k) Summary

Date Prepared: December 6, 2002

Submitter: Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person: Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
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Device Name and Classification:

Trade Name: One Piece Pediatric Arterial Cannula
Models 77006 and 77106

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices: K840001
Arterial Cannula
7000 Series
8, 10, 12, 14, 16, 18, 20, 22, 24, 26 Fr.
Pediatric and Adult Sizes

Device Description:
The One Piece Pediatric Arterial Cannula Models 77006 and 77106 are 6 Fr., flexible, thin-walled cannula with wire wound bodies and a 9" overall length. They have a beveled tip that is made as part of the PVC body. There are depth markings located at 1 cm increments. A tip orientation line indicates the direction of the bevel for location once the cannula is inside the body. The proximal end of the cannula terminates in a 1/4" barbed connector that can be either vented or non-vented. The model 77006 is vented and the model 77106 is non-vented. The proximal end connector on these models is also molded as part of the body.

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Indication for Use
These cannulae are intended for use in perfusion of the ascending aorta during cardiopulmonary bypass, up to six hours or less.

Comparison to Predicate Device
The predicate devices are cannulae with a thin walled tip attached to a flexible PVC body and having both 1/4 " and 3/8" connectors. There was an indexing line for determining tip orientation when the cannula is in the aorta. There was a molded plastic vent plug to allow venting before connection to the perfusion line. The overall length of the cannula was 7". The predicate devices had the same indication for use.

Summary of Performance Data
In vitro visual, dimensional, simulated use and functional testing was used to establish the performance characteristic of the modifications of this device from previously marketed devices. Visual inspection for defects, dimensional testing of the cannula and markings, water and air leak testing, and various bend tests were performed and the results found acceptable.

Conclusion
Medtronic Perfusion Systems has demonstrated that the Arterial One Piece Pediatric Cannula Models 77006 and 77106 are substantially equivalent to predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2003

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Drive N.
Minneapolis, MN 55428-1088

Re: K024069
Trade Name: One Piece Pediatric Arterial Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular cannula
Regulatory Class: Class II (two)
Product Code: DWF
Dated: December 6, 2002
Received: December 10, 2002

Dear Mr. Bennett:

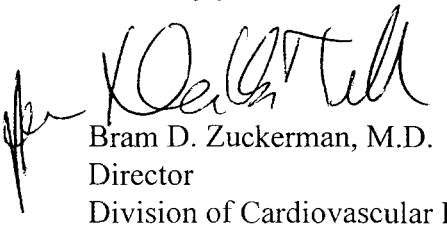
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K024069

510(k) Number (if known): _____

Device Name: One Piece Pediatric Arterial Cannula

Models 77006 and 77106

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024069